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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/841,963	04/25/2001	Dennis K. Watson	10545-015-999	6865
20583	7590	04/20/2004	EXAMINER	
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			SCHULTZ, JAMES	
			ART UNIT	PAPER NUMBER
			1635	

DATE MAILED: 04/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary

Application No.

09/841,963

Applicant(s)

WATSON ET AL.

Examiner

J. Douglas Schultz

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 April 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-39 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |



DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-3, drawn to a modified ets2 protein containing repressor elements, classified for example in class 514, subclass 1.
- II. Claims 4-7, drawn to a nucleic acid encoding ets2 and cells containing said nucleic acid, classified for example in class 536, subclass 23.1.
- III. Claims 8 and 9, drawn to methods of making ets2, classified for example in class 435, subclass 91.1.
- IV. Claims 10 and 11, drawn to antisense molecules targeting ets2, classified in class 536, subclass 24.5.
- V. Claims 12-15, drawn to ribozymes that cleave ets2, nucleic acid constructs comprising said ribozymes, and delivery complexes comprising same, classified in class 536, subclass 23.1.
- VI. Claims 16-19, 25 and 30, drawn to methods of diagnosing cancer comprising detecting ets2 gene product, classified in class 435, subclass 6.
- VII. Claims 20, 21, 24, 25, 26, 29-33 and 36-39, drawn to methods of preventing cancer comprising inhibiting the expression of ets2 optionally using antisense oligos, classified in class 514, subclass 44.
- VIII. Claims 22, 23, 25, 27, 30, 31, 34, and 36, drawn to methods of treating cancer comprising administering an antagonist to ets2, classified in class 514, subclass 1.

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- IX. Claims 28, and 30-33, and 36-39, drawn to methods of sensitizing cancer cells to a treatment comprising administering modified ets2 protein, classified in class 514, subclass 1.

The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups I, II, IV, and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions.

Group I claims the modified polypeptide ets2. Group II specifically claims the polynucleotide encoding said polypeptide. Group IV is drawn to antisense oligos that recognize the nucleic acid of Group II. Group V is drawn to ribozymes that recognize the nucleic acid of Group II. Group I is considered to be unrelated to Groups II-IV, because the polypeptide of Group I is a different compound and thus has a different mode of operation than the nucleic acid of Groups II-IV, and has not been disclosed as being useful with any of Groups II, IV, or V. Furthermore, Groups II, IV and V are independent because they are different sequences, each sequence claimed is structurally and functionally independent and distinct because each sequence is chemically different, and thus each sequence functions differently in the claimed inventions. The nucleic acid of Group II, the antisense of Group IV, and the ribozyme of Group V are directed to products that are different both physically and functionally from each other, are not required for the use of one with the other, and are therefore unrelated. Furthermore, a search of more than one (1) of the genera of compounds claimed presents an undue burden on the Patent

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and Trademark Office due to the complex nature of the search and corresponding examination of more than one (1) of the claimed genera.

Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Restriction among groups drawn to different methods is proper because these methods constitute patentably distinct inventions because each group has steps and assays not required of any of the other groups.

The inventions of Group III and those of Groups VI-IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the methods of Groups VI-IX differ from one another because the method of each group contains steps that are not found in any of the other Groups and thus have different modes of operation, and because they are not disclosed as useful together, restriction is proper. Group III contains steps directed to making the compound that are not shared by any other Groups. Group VI comprises detecting the presence of ets2, which is not required of any other Group. Group VII requires optionally inhibiting with ets2-directed antisense, which is not required of any other Group. Group VIII requires administering an antagonist to ets2 protein, which is not required of any other Group. Group IX requires administering modified ets2 protein, which is not required of any other Group. Thus, the steps required in said methods would be materially different/which is not required of any other groups, and a search and examination of all such methods in one patent application would result in an undue burden, since the searches

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for the methods are not co-extensive, the classification is different, and the subject matter and steps are divergent.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Further, a search and examination of all these products in one patent application would result in an undue burden, since the searches for the methods are not co-extensive, the classification is different, and the subject matter and steps are divergent.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Douglas Schultz whose telephone number is 571-272-0763.

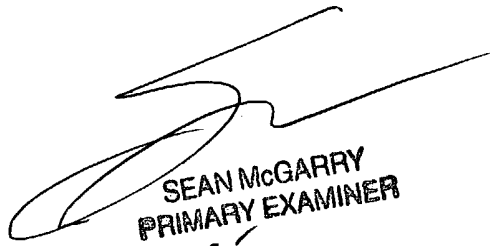
The examiner can normally be reached on 8:00-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 571-272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

James Douglas Schultz, PhD



SEAN MCGARRY
PRIMARY EXAMINER
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